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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/728,327	JORGENSEN ET AL.	
	Examiner	Art Unit	
	KARLHEINZ R. SKOWRONEK	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *37-45 and 48-67* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *37-45 and 48-63* is/are rejected.

8)☒ Claim(s) *64-67* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 37-45 and 48-67 are pending.

Claims 1-36 and 46-47 are cancelled.

Claims 37-45 and 48-67 have been examined.

Claims 37-45 and 48-63 are rejected.

Claims 64-67 are objected to.

Priority

This application was filed on 01 December 2000 and is a continuation of Application No. 09/082201, filed on 20 May 1998 and claims priority to earlier filed Provisional Application No. 60/047,213, filed on 20 May 1997.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 23 August 2010 was filed after the mailing date of the First Action on the Merits following RCE on 18 February 2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claim 47 as introducing new matter under 35 USC 112, first paragraph is withdrawn in view of the cancellation of claim 47.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is reiterated from the previous action.

Claims 37-41, 44-45, 48, 51-54, and 56-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei.et al. (US PAT 6,544,727) in view of Brown (US PAT

4,530,691) in view of Kobashi (U.S. PAT 5,428,993), in view of DeVries (US PAT 4, 379, 452) in view of Siegal (S.S. PAT 4,450,375) and in view of Brown et al. "'883" (US PAT 5730883, IDS 1/18/2002, Cit A82)

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution module and a plurality of sensors. In some embodiments, the sensors include pressure, optical, mass flow, temperature, volume determination or volume detection devices. In some embodiments, supply containers store process chemicals. In some embodiments, process chemicals are selected from the group of citric acid, sodium phosphate, sodium chloride, water, polyethylene glycol, saline, isotonic buffers, glycan modifying enzymes, and glycan modifying enzyme buffers . In some embodiments, the processing module comprises a centrifuge system. In some embodiments, the processing module includes a heat transfer system. In some embodiments, the processing module includes a processing chamber. In some embodiments, the processing module includes a variable-volume processing chamber. In some embodiments, the processing module includes an expressor system. In some embodiments, the system comprises a waste module. In some embodiments, the fluid distribution module comprises a plurality of pumps adapted to the control module and the supply container. In some embodiments, the fluid distribution module comprises a pump for transferring fluid through the fluid distribution module.

Hei discloses a system for the decontamination of biological fluids (e.g., blood) (abstract and col. 66-68). Hei discloses a supply module (fig. 51, elements 508, 539,

and 560). Hei discloses a cell module (fig. 51, elements 500, 528, and 538). Hei discloses a processing module (e.g., element 538 of fig. 51; a block disclosed on fig. 1 and 3; an element where blood and a chemical is mixed on fig. 20-C). Hei discloses a control module (fig; 51, element 550). Hei discloses a plurality of conduits connecting the supply module to the processing module, and the cell module to the processing module (fig. 49-5 1 and 20A-C). Hei discloses a plurality of valves adapted to the control module and other modules (ports, see fig. 49-51,20A-C, and 37). Hei discloses a plurality of sensors, and specifically a sensor calculating the volume and weight of fluids (col. 65, line 30-47). Hei disclose controlling temperature (col. 71, line 63-65; col. 72, line 55-64), flow (col. 66, line 40-65) and volume (col. 68, line 14-40) and an optical device (col. 100, line 28-38). Hei discloses supply containers containing process chemicals (fig. 20, 37, and 49-51; col. 68, line 14-67). Hei discloses phosphate salts, HEPES, citrates, physiological buffers, and anticoagulants (col. 69-70, col. 66, line 40-44). Hei discloses sterile docking, sterile filters, resin (chemical), sterile bags, sterile tubes, sterile tubing, and housing (col. 97, line 29-38 and claim 28). Hei discloses an inline filter (claims 1 and 21). Hei discloses a centrifuge system (fig. 49-51, element 520). Hei discloses a heat transfer system (col. 72, line 53-67). Hei discloses a processing chamber (element 538, fig. 51 and fig. l). Hei discloses a variable-volume processing chamber (fig. 20 and 37; col. 97, line 40-65). Hei discloses an expression system (col. 97, line 40-67). Hei discloses a waste module (a mesh pouch) (col. 121, line 45-61). Hei discloses pumps (elements 51, 6, 506, 536, 526, and 556 of fig. 51). Hei discloses the blood cells as being erythrocytes (col. 12, line 18).

Hei does not show a variable volume processing chamber that is under control of a controller.

Brown et al. shows an apheresis system comprising a variable-volume processing chamber and a controller that controls the volume of the processing chamber (Abstract). Brown et al. shows the chamber advantageously provides an area of a blood sedimentation surface that is greater than an interface surface that maximizes blood cell separation and minimizes platelet separation during red blood cell separation and collection (abstract).

Although Hei discloses sensors for calculating weight and volume of reinfused fluids and defining quantity of blood cells (col. 68, line 14-24; col. col. 65, line 30-47), Hei does not specifically disclose a weight sensor or confirming the correct delivery of a chemical by measuring a change in weight. Hei et al. does not show a fluid distribution module comprising a plurality of ports.

Kobashi discloses a weight sensor for chemical reagents to be used in automatic analyzers that confirms correct delivery of a chemical by measuring change in weight (for example, column 2, lines 1-25).

DeVries shows fluid distribution through conduits for processing cells. DeVries shows the fluid distribution module comprises a plurality of conduits (figure 4). DeVries shows the system is closed to environmental contaminants and providing for sterile processing (col. 2, lines 30-32). DeVries shows the fluid distribution module comprises a pump (col. 5, line 50-53). DeVries shows the plurality of conduits comprises a single use disposable device (col. 3, line 50). DeVries shows an advantage of closed fluid

distribution module is that it simplifies the handling of complex fluid systems and protects the system from contamination from the environment (col. 2, lines 32-35).

Hei in view of Kobashi and in view of DeVries do not show a plurality of sealed channels in fluid communication with the plurality of ports for transferring fluid from one port to another port of the plurality of ports at least a portion of each of the plurality of sealed channels defined by a flexible membrane; a plurality of valves, each valve of the plurality of valves associated with a respective port and aligned for displacement of the flexible membrane to control transfer of fluid, the valves adapted to the control module.

Siegal shows fluid control module comprising a plurality of channels and ports. Siegal shows that the channels are in fluid communication with the plurality of ports. The ports are capable of being connected to conduits. Siegal shows a portion of the channels is defined by a flexible membrane (col. 2). Siegal shows a plurality of valves. Siegal shows each valve of the plurality is associated with a port and aligned such that displacement of the flexible membrane controls fluid transfer (figure 5). Figure 5 shows an exploded view of the Siegal fluidics control module. Member 24' is the flexible membrane. Members 22' indicate the plurality of channels. Members 16a-d are the ports. Members 29a-d form a plurality of valves in combination with the flexible membrane. Siegal shows that the valves are adapted to a control and the operation of the valves is regulated by the control by an electrical control signals on a plurality of piezoceramic benders that cooperate with an impacting member to regulate fluid transfer (col. 3, line 40-53). Siegal shows that the fluidics control module piezo-electric transducer is outside the valve reservoir such that the transducer does not contact the

fluid to provide a structure that is simple, economical to manufacture and highly effective for the intended purpose of rapidly and accurately controlling fluid flow (col. 1, line 37-42). Siegal suggest the fluidics control module can be adapted to biomedical applications (col. 5, line 23).

The '883 patent discloses a system for blood cell separation that comprises a controller in communication with a plurality of sensors (col. 7, line 38-43). '883 shows that controller maintains processing conditions (col. 8, line 31-40). '883 shows automated process controller that can gather and generate more detailed information and control signals to aid the operator in maximizing processing and separation efficiencies (col. 1, line 55-60).

It would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to modify the system of Hei to include a processing chamber with a controllable variable-volume of Brown et al. because Brown et al shows a variable-volume processing chamber advantageously provides an area of a blood sedimentation surface that is greater than an interface surface that maximizes blood cell separation an minimizes platelet separation during red blood cell separation and collection. It would have been further obvious, to one of ordinary skill in the art, at the time the invention was made, to modify the system of Hei to include the reagent weight sensor of Kobashi. One of ordinary skill in the art would have been motivated to do this because, as suggested by Kobashi, it can prevent the wasting of reagents (for example, see abstract). It would have further obvious to modify the system of Hei et al. and the reagent weight sensors of Kobashi et al. with the fluid distribution module of Siegal and

the fluid distribution via conduits of DeVries because Siegal shows an advantage of the fluid distribution module is that it is simple, economical to manufacture and highly effective for the intended purpose of rapidly and accurately controlling fluid flow. It would have been further obvious to one of ordinary skill in the art at the time of invention to modify the system of Hei et al. and the reagent weight sensors of Kobashi et al., the fluid distribution module of Siegal and the fluid distribution via conduits of DeVries with the controller of '883 because '883 shows automated process controller that can gather and generate more detailed information and control signals to aid the operator in maximizing processing and separation efficiencies.

Response to Argument

Applicant's arguments filed 23 September 2011 have been fully considered but they are not persuasive. Applicant argues the combination of Hei, in view of Brown, in view of Kobashi in view of DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 does not show the claim as amended. The argument is not persuasive because 883 shows a system for blood cell separation that comprises a controller in communication with a plurality of sensors maintains processing conditions as instantly claimed

The following rejection is reiterated from the previous action.

Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, in view of Brown, in view of Kobashi in view of DeVries, and in view of Siegal as

applied to claims 37-41, 44-45, 48, 51-54, and 56-63 above, and further in view of Matkovich, US 5,126,054.

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution module and a plurality of sensors. In some embodiments, filter with a median pore of about 0.2 microns is positioned between the supply module and the processing module. In some embodiments, the process chemicals are sterile. In some embodiments, a leukocyte depletion filter is positioned between the cell and processing modules.

Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal shows the system of claims 37-41, 44-45, 48, 51-54, and 56-63, as set forth above.

Hei discloses a filter (claims 1 and 21), but Hei, in view of Kobashi et al., in view DeVries, and in view of Siegal do not disclose a filter having a median pore diameter of about 0.2 microns and a leukocyte depletion filter.

Matkovich discloses the filtration of blood components into a receiving bag (col. 1, line13-17 and claim 1). Matkovich further discloses removing leukocytes by filtration from blood (leukocyte depletion) (col. 1, line 13-17; col. 5-6, bridging paragraph). Matkovich discloses a filter having 0.2 micron pores (claims 5 and 10).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 above to use a filter to deplete leukocytes, such as taught by Matkovich, where

the motivation would have been to remove harmful components, as taught by Matkovich.

Response to Argument

Applicant's arguments filed 23 September 2011 have been fully considered but they are not persuasive. Applicant argues the combination of Hei, in view of Brown, in view of Kobashi in view of DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 in further view of Matkovich does not show the claim as amended. The argument is not persuasive for the reasons provided above

The following rejection is reiterated from the previous action.

Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 above, and further in view of Burney et al. (U.S. Pat. 3478673) and in view of Wrasidlo et al. (U.S. Pat. 4937196).

Claim 49 is directed to a compressor, an air reservoir, and a filter. In claim 50, the filter of claim 49 has a 0.2 micron pore size.

Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 above show a system for processing biological cells.

Hei,, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal above do not show a compressor, air reservoir, or 0.2 micron filter.

Burney et al. shows that a source of compressed air can be generated and maintained using a compressor and air reservoir (col. 3, line 27-28). Burney shows that the stored air is cleaned by passing the air through a filter (col. 3, line 20-23).

With respect to claim 50, Burney et al. does not show a 0.2 micron filter.

Wrasidlo et al. is directed to a system from cell processing. Wrasidlo et al. shows that a 0.2 micron filter fitted to an air conduit is pumped into a reservoir leading to pressurization of the reservoir (col. 11, line 28-35). Wrasidlo et al. discloses that the 0.2 micron filter assures that sterile air is introduced to the reservoir (col. 11, line 32-34).

It would have been obvious to one of ordinary skill in the art to modify the system of Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 above with the compressor, air reservoir and 0.2 micron filters to provide a source of sterile air of Burney et al. and Wrasidlo et al. because all the claimed elements were known in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.

Response to Argument

Applicant's arguments filed 23 September 2011 have been fully considered but they are not persuasive. Applicant argues the combination of Hei, in view of Brown, in view of Kobashi in view of DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 in further view of Burney et al. and in view of Wrasidlo et al.

does not show the claim as amended. The argument is not persuasive for the reasons provided above.

The following rejection is reiterated from the previous action.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, in view of Brown, in view of Kobashi et al., in view of Brown, in view DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 above, and further in view of Hudak, US 5,641,637.

The claims are directed to a system for processing biological cells, comprising a supply module, a cell module, a processing module, control module, a fluid distribution module and a plurality of sensors. In some embodiments, blood cells are A, B, or AB genotype.

Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal shows the system of claims 37-41, 44-45, 48, 51-54, and 56-63, as set forth above.

Hei, in view of Brown, in view of Kobashi et al., in view DeVries, and in view of Siegal above do not disclose the blood cell genotypes A, B, or AB.

Hudak discloses a method for preparing cells. Specifically, Hudak discloses rare genotype cells (e.g., AB genotype) (col. 2, line 45-52).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the system of Hei, in view of Kobashi et al., in view DeVries, and in view of Siegal applied to claims 37-41, 44-45, 48, 51-54, and 56-63 above to use

AB cells, such as taught by Hudak, where the motivation would have been to provide hospitals with rare cell genotype blood, as taught by Hudak, col. 2, line 45-52.

Response to Argument

Applicant's arguments filed 23 September 2011 have been fully considered but they are not persuasive. Applicant argues the combination of Hei, in view of Brown, in view of Kobashi in view of DeVries, and in view of Siegal as applied to claims 37-41, 44-45, 48, 51-54, and 56-63 in further view of Hudak does not show the claim as amended. The argument is not persuasive for the reasons provided above.

Allowable Subject Matter

Claims 64-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Primary Examiner, Art Unit 1631

4 November 2011